



Council for Responsible Nutrition

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May 23, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: Docket No. 01D-0058,
Comments on Guidance on Structure/Function Rule**

The Food and Drug Administration (FDA) has requested comments on the need for and potential content of new guidance that may be developed regarding application of the final rule published on January 6, 2000, on structure/function claims for dietary supplements. The FDA notice requesting comment specifically noted that the guidance currently being considered would not include issues relating to substantiation requirements, which will be addressed in separate guidance at a later date.

The Council for Responsible Nutrition (CRN) is a trade association representing more than 100 manufacturers in the dietary supplement industry. On behalf of our member companies, CRN has worked closely with FDA over the years on issues relating to product safety and claims, including the issues relating to structure/function statements.

CRN believes that FDA has been very complete in its discussion of the permissible scope of structure/function statements, in the final rule published in January 2000 and also in a number of public meetings before and after that date. FDA guidance and views have also been provided in the context of "courtesy letters" sent to numerous companies in the past six or seven years.

In contrast, there are other issues regarding which the agency has provided relatively little guidance, including the critical matter of the criteria for substantiation. There are also other urgent matters requiring FDA's attention, in its effort to fully implement the Dietary Supplement Health and Education Act of 1994 (DSHEA). Many of these matters were articulated in the Strategic Plan outlined by FDA's Center for Food Safety and Applied Nutrition in January 2000.

CRN respectfully suggests that FDA's limited resources would be more effectively deployed against some of these other objectives, rather than being spent in further elaboration of the agency's already extensive guidance on the scope of structure/function

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statements. CRN and its member companies remain committed to working with FDA to fully implement DSHEA in the most expeditious and effective manner possible, and we look forward to further cooperative efforts on the many issues still requiring resolution.

Sincerely,

A handwritten signature in cursive script that reads "A Dickinson". The signature is fluid and elegant, with the first letter "A" being particularly large and stylized.

Annette Dickinson, Ph.D.

Vice President, Scientific & Regulatory Affairs